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EXAMINER
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MORGAN, ROBERT W

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3626

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Notice to Applicant***

1. In amendments filed 2/11/08, 11/19/08 and 1/16/09, the following has occurred: claims 106, 109, 110, 112-116, 118, 121, 122, 123, 125, 126, 129, 135-137 and 144 have been amended, claims 1-103 have been canceled and claims 104-156 have been added. Now claims 104-156 are presented for examination.

### ***Claim Rejections - 35 USC § 112***

2. The rejections under 35 USC § 112, second paragraph have been withdrawn by the Examiner based on the changes made by the Applicant to the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 104-111, 113-116, 118-122, 123-124, 126-128, 129, 130, 132, 134-136, 139-140, 142, 148-149, 152 and 153-154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) in view of Dorne (5,325,293).

(A) As per claims 104-105, Evans discloses an apparatus for creating and maintaining patient data electronically and for generating codes (Fig. 20, Abstract) comprising:

(a) a point of care system to capture patient data at a point of care, wherein the point of care system is a pen-based computer, a laptop, or a desktop computer (Fig. 24, col. 13 lines 12-30, col. 16 lines 2-20), wherein the point of care system comprises;

Art Unit: 3626

(i) a patient data capture means communicating with a practice guidelines means to assist the practitioner in selecting an appropriate course of action, including diagnoses and procedures, for a patient in real-time (Fig. 9, Fig. 24, col. 2 lines 22-44, col. 7 line 40 to col. 8 line 17, col. 11 lines 36-64, col. 16 lines 2-20) (reads on "a prompting means to repeatedly generate real-time prompts for various information including medical services being provided");

(ii) a patient data repository in communication with the point of care System to store and organize the patient data (Fig. 24, Col. 4 line 64 to col. 5 line 27, col. 16 lines 2-20);

(iii) wherein said patient data capture means includes:

(1) a practice guidelines means for assisting the practitioner in selecting the appropriate course of action (Fig. 9, Fig. 24, col. 2 lines 22- 44, col. 7 line 40 to col. 8 line 17, col. 11 lines 9-30, col. 11 lines 36-64, col. 16 lines 2-20) (reads on "a guiding means");

(2) a medication manager means for providing a warning of a contraindication and alerting the physician to the contraindication, wherein in view of the warning, the physician can investigate the effects of the medication by clicking on the results button (Fig. 21-22, col. 11 line 65 to col. 12 line 35) (reads on "a reminding means"); and

(3) a graphical user interface for a diagnosis module and procedure module, wherein the physician can enter multiple diagnoses and procedures based on a description of the diagnoses and procedures, wherein the diagnoses and procedures correspond with codes, wherein the physician also obtains insurance information from a patient, wherein the codes include ICD9 diagnosis codes and CPT procedure codes (Fig. 13-14, 20, col. 5 lines 35-40, col. 9 lines 1-13, col. 11 lines 36-64) (reads on "a soliciting means") (It is noted that ICD9 and CPT codes are used for the purpose of billing an insurance company for the medical services provided).

Art Unit: 3626

Evans fails to expressly disclose an electronic means including a processing means for calculating intermediate values based on said recorded information and a processing means for using said intermediate values to generate said billing code.

Dorne discloses an apparatus for correlating billing codes with medical procedures comprising: an electronic means including a processing means for calculating intermediate values based on said recorded information (Fig. 1, col. 3 lines 18-38, col. 11, lines 30-63; col. 20-46) and a processing means for using said intermediate values to generate said billing code (Fig. 1, col. 3 lines 18-38, col. 20-46).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Dorne within the apparatus of Evans with the motivation of providing an apparatus for rapidly and simply correlating CPT codes with medical procedures performed during patient examination which does not require a thorough understanding of the nomenclature used by the CPT coding system (Dorne; col. 3 lines 10-15).

(B) As per claim 106, Evans discloses a physician selecting an appropriate body system, wherein the appropriate body system is used for determining a description of a medical service (reads on "soliciting underlying information comprising details of a patient history, details of a patient examination and/or details of medical decision making regarding a patient diagnosis, details of medical tests to describe, diagnose and/or treat the patient, information used for clinical research, information used for quality assurance, and/or information used to compile patient care data base information") (Fig. 20, col. 11, line 36-64).

Evans and Dorne do not explicitly disclose repeating said prompting, obtaining, and recording step.

Art Unit: 3626

Official Notice is taken that it would have been obvious to a person of ordinary skill in the art to repeat these steps for obtaining as much accurate data as possible from a patient, thereby making it easier to complete the information gathering.

The remaining features of claim 106 repeat the same limitations of claim 104, and are therefore rejected for the same reasons as claim 104, and incorporated herein.

Evans and Dorne teach an electronic means including a processing means for calculating intermediate values based on said recorded information (see: Dorne: Fig. 1, col. 3 lines 18-38, col. 11, lines 30-63; col. 20-46).

Evans and Dorne do not expressly the underlying information comprising details of a patient history...and/or information used to compile patient care data base information. However, this difference is only found in the nonfunctional descriptive material and is not functionally involved in the steps recited. The calculating step would be performed the same regardless of the data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 UPSQ2d 1031 (Fed. Cir. 1994). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to solicit different of usable information because such data does not functionally relate to the steps in the apparatus claimed and because the subjective interpretation of the data does not patentably distinguish the claimed invention.

(C) Claims 107-108 repeat the limitations of claims 104-105, and is therefore rejected for the same reasons as those claims, and incorporated herein.

(D) As per claim 109, Dorne discloses the step of calculating a billing code calculates an

Art Unit: 3626

appropriate code from the United States Health Care Financing Administration (now known as Center for Medicare and Medicaid Services) codes (col. 1, lines 15-30).

(E) Claims 110-111 repeat the limitations of claims 104-106, and is therefore rejected for the same reasons as those claims, and incorporated herein.

(F) Claim 113 repeats the limitations of claims 104, 106, and 109, and is therefore rejected for the same reasons as those claims, and incorporated herein.

(G) As per claim 114, Evans discloses an electronic apparatus for use in connection with an encounter between a medical practitioner and a patient comprising:

(a) electronic means for prompting the medical practitioner regarding data to be obtained from the patient regarding patient care and corresponding HCFA billing codes, said data including the individual data elements needed to calculate and derive the final billing code based on billing requirements imposed by HCFA, said data constituting more than just the final billing code for the medical services (col. 11 lines 36-64);

(b) a data storage and access means for storing said data from the patient and providing access to (Fig. 1):

(i) a menu section comprising at least one of history, physical examination, and medical decision making questions, said menu section related to said means for prompting the medical practitioner (Fig. 5);

(ii) payer mandated requirement codes (Fig. 20);

(iii) scores based in part on results from responses to said menu section (Fig. 20 - CPT codes);

(iv) an algorithm for linking and processing said requirement codes with said scores (Fig. 20, col. 11 lines 36-64 - modules);

Art Unit: 3626

(v) a resultant code based in part on said linked and processed requirement codes and scores (Fig. 20 - ICD-9 codes).

Evans does not explicitly refer to HCFA.

Dorne discloses the step of calculating a billing code calculates an appropriate code from the United States Health Care Financing (col. 1, lines 15-30).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Dorne within the apparatus of Evans with the motivation of providing an apparatus for rapidly and simply correlating CPT codes with medical procedures performed during patient examination which does not require a thorough understanding of the nomenclature used by the CPT coding system (Dorne; col. 3 lines 10-15).

(H) Claim 115 repeats the limitations of claim 109, and is therefore rejected for the same reasons as claim 109, and incorporated herein.

(I) As per claim 116, Evans discloses collecting data over the Internet (Fig. 24). It is inherent that collecting data over the Internet includes a timer in order to time out the data session when a user has not entered data over a certain period of time.

(J) As per claim 118, Evans discloses noting dictation and for later appending dictated notices with said responses (Fig. 13-14).

(K) As per claims 119-120, Evans discloses a history score and a physical examination score (Fig. 7) and a final score showing scores that are outside of a range (Fig. 7).

(L) As per claims 121-122, Evans discloses dictated and free form text information based on said responses of the physical examination (Fig. 13-14, col. 8 line 29 to col. 9 line 13).

(M) Claims 123 and 129 repeat the limitations of claims 49 and 59, and is therefore rejected for



Art Unit: 3626

the same reasons as those claims, and incorporated herein.

(N) As per claim 124, Evans discloses CPT and ICD-9 codes for billing (Fig. 20).

(O) Claims 126-128 repeat the limitations of claims 104 and 109, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

(P) Claims 131-132 repeat the limitations of claim 104, and is therefore rejected for the same reasons as claim 104, and incorporated herein.

(Q) As per claim 130, Evans discloses calculating scores, said scores based in part on said requirements and related to billing codes and said gathered information (Fig. 20, col. 11 lines 36-64), electronically linking said gathered information, said requirements, and said scores for processing (Fig. 20; col. 11 lines 36-64), processing said linked information with an algorithm to compute a final score (Fig. 20, col. 11 lines 36-64), and providing a copy of said final score and other gathered information (Fig. 20, col. 11 lines 36-64).

The remaining features of claim 130 repeat the limitations of claims 104 and 114, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

(R) Claims 138-141 repeat the limitations of claim 104, and is therefore rejected for the same reasons as claim 104, and incorporated herein.

As per claim 148, it repeats the limitations of claim 122, and is therefore rejected for the same reasons as those claims, and incorporated herein.

As per claim 149, it repeats the limitations of claim 110, and is therefore rejected for the same reasons as those claims, and incorporated herein.

As per claim 152, it repeats the limitations of claim 128, and is therefore rejected for the same reasons as those claims, and incorporated herein.

Art Unit: 3626

As per claims 153-154, they repeat the limitations of claim 139, and is therefore rejected for the same reasons as those claims, and incorporated herein.

4. Claims 112, 131, 138, 141, 144-146, 150-151 and 155-156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) in view of Dorne (5,325,293) and Peters et al. (5,893,098).

(A) As per claims 112, 131, and 141, Evans discloses an apparatus for creating and maintaining patient data electronically and for generating codes (Fig. 20, Abstract) comprising:

(a) a point of care system to capture patient data at a point of care, wherein the point of care system is a pen-based computer, a laptop, or a desktop computer (Fig. 24, col. 13 lines 12-30, col. 16 lines 2-20) (reads on "an electronic means"), wherein the point of care system comprises;

(i) a patient data capture means communicating with a practice guidelines means to assist the practitioner in selecting an appropriate course of action, including:

diagnoses and procedures, for a patient in real-time, wherein the physician can enter results of a current examination of a patient, including family history, current medications and complaints based on a graphical user interface (Fig. 5 - see the problem list, history, etc. - a form of "series of inquires") (Fig. 9, Fig. 24, col. 2 lines 22-44, col. 5 lines 1-28, col. 6 lines 10-36, col. 7 line 40 to col. 8 line 17, col. 11 lines 36-64, col. 16 lines 2-20) (reads on "a prompting means");

(ii) said patient data capture means including:

(1) a practice guidelines means for assisting the practitioner in selecting the appropriate course of action (Fig. 9, Fig. 24, col. 2 lines 22- 44, col. 7 line 40 to col. 8 line 17, col. 11 lines 9-30, col. 11 lines 36-64, col. 16 lines 2-20) (reads on "a guiding means");

(2) a medication manager means for providing a warning of a contraindication and alerting the

Art Unit: 3626

physician to the contraindication, wherein in view of the warning, the physician can investigate the effects of the medication by clicking on the results button (Fig. 21-22, col. 11 line 65 to col. 12 line 35)(reads on "a reminding means"); and

(3) a graphical user interface for a diagnosis module and procedure module, wherein the physician can enter multiple diagnoses and procedures based on a description of the diagnoses and procedures, wherein the diagnoses and procedures correspond with codes, wherein the physician also obtains insurance information from a patient, wherein the codes include ICD9 diagnosis codes and CPT procedure codes (Fig. 13-14, 20, col. 5 lines 35-40, col. 9 lines 1-13, col. 11 lines 36-64) (reads on "a soliciting means")

(It is noted that ICD9 and CPT codes are used for the purpose of billing an insurance company for the medical services provided). (ii) a patient data repository in communication with the point of care system to store and organize the patient data (Fig. 24, col. 4 line 64 to col. 5 line 27, col. 16 lines 2-20);

Evans does not expressly disclose a calculating means for calculating the Evaluation and Management billing code which meets the billing requirements imposed by said payer mandates, said billing code based on information recorded from the medical interview, although Evans does suggest using ICD9 and CPT codes.

Dorne discloses an apparatus for correlating billing codes with medical procedures comprising: an electronic means including a processing means for calculating intermediate values based on said recorded information (Fig. 1, col. 3 lines 18-38, col. 20-46) and a processing means for using said intermediate values to generate said billing code (Fig. 1, col. 3

Art Unit: 3626

lines 18-38, col. 20-46), wherein calculating a billing code includes calculating an appropriate code from the United States Health Care Financing (HCFA) (col. 1, lines 15-30).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Dorne within the apparatus of Evans with the motivation of providing an apparatus for rapidly and simply correlating CPT codes with medical procedures performed during patient examination which does not require a thorough understanding of the nomenclature used by the CPT coding system (Dorne; col. 3 lines 10-15).

Evans and Dorne do not expressly disclose calculating means for calculating further prompting for inquiries to make of the patient using at least some of the preceding responses.

Peters discloses asking questions in a survey including branched-to questions linked to another question or questions such that the branched-to question or questions will only be required to be answered by a respondent user if the respondent user gives a predetermined answer to the question or series of questions to which the branched-to question is linked (col. 5 line 54 to col. 6 line 27).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Peters within the apparatus taught collectively by Evans and Dorne with the motivation of preventing the user from having to wade through a series of displayed questions to find the ones that are relevant to the user, thus saving time (Peters; col. 6 lines 24-27).

Evans, Dorne and Peters teach an electronic means including a processing means for calculating intermediate values based on said recorded information (Fig. 1, col. 3 lines 18-38, col. 11, lines 30-63; col. 20-46).

Art Unit: 3626

Evans, Dorne and Peters do not expressly the underlying information comprising details of a patient history...and/or information used to compile patient care data base information. However, this difference is only found in the nonfunctional descriptive material and is not functionally involved in the steps recited. The calculating step would be performed the same regardless of the data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 UPSQ2d 1031 (Fed. Cir. 1994). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to solicit different of usable information because such data does not functionally relate to the steps in the apparatus claimed and because the subjective interpretation of the data does not patentably distinguish the claimed invention.

(B) As per claims 138 and 144, the Examiner discloses that scannable forms are well known in the art of surveying.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the modification within the apparatus taught collectively by Evans, Dorne, and Peters with the motivation of efficiently obtaining user results.

As per claims 145-146, they repeat the limitations of claims 109 and 126, and is therefore rejected for the same reasons as those claims, and incorporated herein.

As per claims 150-151, they repeat the limitations of claim 112, and is therefore rejected for the same reasons as those claims, and incorporated herein.

As per claims 155-156, they repeat the limitations of claim 144, and is therefore rejected for the same reasons as those claims, and incorporated herein.

Art Unit: 3626

5. Claims 117 and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) and Dorne (5,325,293), and further in view of Official Notice.

(A) As per claim 117, Evans and Dorne do not expressly disclose software for enabling a user of said apparatus to self-generate questions in any particular order.

It is respectfully submitted that it is well known in the art of generating questionnaires to allow a user to generate questions in a particular order depending on the user's preference.

The motivation for including this modification within the system taught collectively Evans and Dorne being to provide a user friendly means to allow a user to customize a questionnaire.

As per claim 147, it repeats the limitations of claim 117, and is therefore rejected for the same reasons as those claims, and incorporated herein.

6. Claims 125 and 135-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) and Dorne (5,325,293) as applied to claims 104, 106, and 123, and further in view of Letzt et. al. (5,612,869).

(A) As per claim 125, Evans and Dorne does not explicitly disclose a timer for tracking total time and patient counseling time during said patient encounter, and an algorithm for computing the percent of total time used for counseling.

Letzt discloses an electronic health care compliance assistance comprising a timer for tracking total time and patient counseling time including a Health Care Financial Administration billing code (col. 26, lines 12-28).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Letzt within the system of Evans and Dorne with the

Art Unit: 3626

motivation of decreasing the costs to certain therapies, thereby improving compensation from the patient's insurance.

(B) As per claims 135-136, Evans and Dorne do not explicitly disclose a billing code based in part on comparing a total patient encounter time and a total patient counseling time.

Letzt on the other hand, discloses an electronic health care compliance assistance comprising a timer for tracking total time and patient counseling time including a health care financial administration billing code (col. 26, lines 12-20).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify Evans and Dorne by including a billing code based in part on comparing a total patient encounter time and a total patient counseling time as evidenced by Letzt.

The motivation being to decrease the costs to certain therapies given to a patient, thereby improving compensation from the patient's insurance.

(C) As per claim 137, Evans and Dorne do not explicitly disclose a billing code based in part on comparing a total patient encounter time and a total patient counseling time.

Letzt on the other hand, discloses an electronic health care compliance assistance comprising a timer for tracking total time and patient counseling time including a health care financial administration billing code (col. 26, lines 12-20).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the applicant's invention to modify Evans and Dorne by including a billing code based in part on comparing a total patient encounter time and a total patient counseling time as evidenced by Letzt.

Art Unit: 3626

The motivation being to decrease the costs to certain therapies given to a patient, thereby improving compensation from the patient's insurance.

7. Claim 134 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) and Dorne (5,325,293) as applied to claim 123, and further in view of Kraftson et al. (6,151,581).

(A) As per claim 134, Evans and Dorne do not expressly disclose a scannable form for prompting inquiries.

Kraftson discloses a scannable form for prompting inquiries (col. 5, lines 1-6).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Kraftson within the system of Evans and Dorne with the motivation of providing an efficient means to collect survey data.

8. Claims 142-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (5,924,074) and Dorne (5,325,293) as applied to claims 104 and 106, and further in view of Peters et al. (5,893,098).

(A) As per claims 142-143, Evans and Dorne do not expressly disclose prompting for inquiries to make of the patient using at least some of the preceding responses.

Peters discloses asking questions in a survey including branched-to questions linked to another question or questions such that the branched-to question or questions will only be required to be answered by a respondent user if the respondent user gives a predetermined answer to the question or series of questions to which the branched-to question is linked (col. 5 line 54 to col. 6 line 27).



Art Unit: 3626

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Peters within the apparatus taught collectively by Evans and Dorne with the motivation of preventing the user from having to wade through a series of displayed questions to find the ones that are relevant to the user, thus saving time (Peters; col. 6 lines 24-27).

### ***Response to Arguments***

Applicant's arguments filed 1/16/09 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 1/16/09.

In response to Applicant argument, it is respectfully submitted that the Examiner has applied recited new passages and citations to amended claims 106, 109, 110, 112-116, 118, 121, 122, 123, 125, 126, 129, 135-137 and 144 and newly added claim 145-156 at the present time. The Examiner notes that amended and newly added limitations were not in the previously pending claims as such, Applicant's remarks with regard to the application of Evans, Dorne, Official Notice, Kraftson, Letzt and/or Peter to the amended and newly added limitations are addressed in the above Office Action.

In addition, since the Applicant has not traversed the Examiner Official Notice taken in the previous Office Action (dated 11/20/06), the well known in the art statement is taken to be admitted prior art (MPEP 2144.03 [R-1] section C).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT W. MORGAN whose telephone number is (571)272-6773. The examiner can normally be reached on 9:00 a.m. - 5:30 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Morgan/  
Primary Examiner, Art Unit 3626